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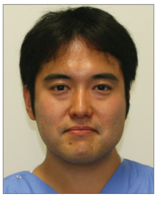
Comparison of aortic annulus dimensions between Japanese and European patients undergoing transcatheter aortic valve implantation as determined by multi-detector computed tomography: results from the OCEAN-TAVI (Optimised transCathEter vAlvular interveNtion) registry and a European single-centre cohort



Yusuke Watanabe[1]*, MD; Marie-Claude Morice[2], MD; Ken Kozuma[1], MD, PhD; Masanori Yamamoto[3], MD, PhD; Hideyuki Kawashima[1], MD, PhD; Fumiaki Yashima[4], MD; Taku Inohara[4], MD; Erik Bouvier[2], MD; Takahide Arai[2], MD, PhD; Keiichi Fukuda[4], MD, PhD; Thierry Lefevre[2], MD; Kentaro Hayashida[4], MD, PhD

1. Teikyo University School of Medicine, Tokyo, Japan; 2. Institut Cardiovasculaire Paris Sud, Massy, France 3. Toyohashi Heart Center, Toyohashi, Japan; 4. Keio University School of Medicine, Tokyo, Japan

KEYWORDS

- aortic annulus measurement
- multi-detector computed tomography
- transcatheter aortic valve implantation

Abstract

Aims: This study sought to compare precise measurements of the aortic valve complex in Japanese and European patients undergoing transcatheter aortic valve implantation (TAVI) using multi-detector computed tomography (MDCT).

Methods and results: Between October 2013 and July 2014, 90 patients undergoing TAVI were prospectively included in the OCEAN-TAVI registry from three Japanese centres. Between March 2009 and December 2012, 181 patients undergoing TAVI at a single French centre were prospectively included in the European cohort. Female sex was more frequently observed in the Japanese cohort (74.4% vs. 44.2%, $p<0.01$). All MDCT-measured annulus dimensions including annulus area (375.9 cm^2 [IQR 333.8-410.7] vs. 472.5 cm^2 [IQR 415.3-536.6], $p<0.01$), left coronary ostium height (13.6 mm [IQR 12.0-15.0] vs. 15.1 mm [IQR 13.5-17.2], $p<0.01$), right coronary ostium height (15.9 mm [IQR 14.5-17.5] vs. 17.7 mm [IQR 16.0-19.7], $p<0.01$), and the sinus of Valsalva (27.2 mm [IQR 25.6-29.5] vs. 32.0 mm [IQR 29.7-34.0], $p<0.01$) were smaller in the Japanese patients.

Conclusions: Japanese patients had a smaller aortic valve complex than European patients. A smaller prosthesis is required for Japanese patients undergoing TAVI. The risks related to these anatomical characteristics should be considered.

**Corresponding author: Teikyo University School of Medicine, 2-11-1 Kaga, Tokyo, 173-8606, Japan. E-mail: yusuke0831@gmail.com*

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Abbreviations

AS	aortic stenosis
BSA	body surface area
IQR	interquartile range
LCC	left coronary cusp
MDCT	multi-detector computed tomography
NCC	non-coronary cusp
OCEAN-TAVI	Optimised transCathEter vAlvular interveNtion-TAVI
RCC	right coronary cusp
SOV	sinus of Valsalva
TAVI	transcatheter aortic valve implantation

Introduction

Transcatheter aortic valve implantation (TAVI) is evolving rapidly with an exponential growth in the number of procedures in European countries[1,2]. However, TAVI has just started to be used in some Asian countries[3,4], and its efficacy and safety in Asian patients has not been thoroughly investigated. Furthermore, Asians have a smaller body size and, consequently, a smaller aortic annulus size and vascular access than their European counterparts. The risks related to these anatomic differences have raised serious concerns about the safety of TAVI in Asian patients.

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This study sought to examine the anatomic features of Asian patients undergoing TAVI and to compare aortic annulus dimensions, determined by multi-detector computed tomography (MDCT), with European patients undergoing the same procedure.

Methods

STUDY POPULATION AND DESIGN

OCEAN-TAVI REGISTRY

The OCEAN-TAVI (Optimised transCathEter vAlvular interveNtion) registry is a Japanese multicentre prospective registry. This registry was initiated to observe and document procedural results and post-procedural outcome of TAVI. The OCEAN-TAVI registry is independent of any industry influence.

Between October 2013 and July 2014, a total of 90 consecutive high-risk Japanese patients with symptomatic severe AS undergoing TAVI using the Edwards SAPIEN XT prosthesis (Edwards Lifesciences, Irvine, CA, USA) at the Teikyo University School of Medicine (Tokyo, Japan, n=20), Keio University School of Medicine (Tokyo, Japan, n=45) and Toyohashi Heart Center (Toyohashi, Japan, n=25) were prospectively included in the OCEAN-TAVI registry. All patients gave written informed consent before the procedure. Inclusion criteria were the presence of symptomatic degenerative AS with a New York Heart Association (NYHA) Class II or greater, a mean gradient >40 mmHg or a jet velocity greater than 4.0 m/s or an aortic valve area <1.0 cm^2 (or an effective orifice area index <0.6 cm^2/m^2). Patients for whom TAVI was deemed to be the best treatment option were selected based on the clinical consensus of a multidisciplinary team consisting of cardiac surgeons, interventional cardiologists, anaesthetists, and imaging specialists. Primary exclusion criteria were the following: bicuspid or non-calcified aortic valve, aortic annulus diameter (echo measurement) <18 mm or >25 mm, severe left ventricular dysfunction (left ventricular ejection fraction <20%), severe aortic regurgitation or dialysis dependence. All 90 patients underwent pre-procedural ECG-gated MDCT scans before TAVI.

THE EUROPEAN SINGLE-CENTRE COHORT

Between March 2009 and November 2012, a total of 545 consecutive high-risk patients with symptomatic severe AS treated with TAVI at the Institut Cardiovasculaire Paris Sud (Massy, France) were prospectively included in the study group designated as the European single-centre cohort. Of these, 181 patients in whom ECG-gated MDCT data were available were finally included in the study.

Patients with severe symptomatic AS (valve area ≤1.0 cm^2) were considered candidates for TAVI if they had a logistic EuroSCORE >20%, if surgery was deemed to be excessively risky due to significant comorbidities, or if other risk factors not captured by these scoring systems (e.g., porcelain aorta) were present. The decision to proceed with TAVI was discussed by a dedicated Heart Team including experienced clinical and interventional cardiologists, cardiovascular surgeons and anaesthesiologists. All patients agreed to participate in the study, and written informed consent was obtained in all cases.

MDCT IMAGE ACQUISITION

THE OCEAN-TAVI REGISTRY

All examinations were performed with multi-detector row CT scanners consisting of 64 rows or greater. The thickness of the reconstructed image was 0.8 mm in the Japanese cohort. Data acquisition, image post-processing, and data interpretation were performed according to the guidelines of the Society of Cardiovascular Computed Tomography[5].

THE EUROPEAN SINGLE-CENTRE COHORT

All examinations were performed using a Philips Brilliance 64-slice MDCT scanner (Philips Medical Systems, Best, The Netherlands). Standard technical parameters were used: gantry rotation time 300 ms, axial coverage 40 mm (64×0.625 mm), 120 kV tube voltage, 850-900 mAs intensity with our modulation, temporal resolution 165 ms. Retrospective ECG gating was performed. Contrast enhancement was achieved using 50-80 ml of Iomeprol 400 mg/ml (Iomeron®). In order to achieve optimal synchronisation, a bolus tracking method was used in the descending aorta. Additional beta-blockade was not administered in any case due to potential haemodynamic instability in severe AS.

MDCT ANALYSIS

All MDCT data from the European and Japanese cohorts were transmitted to an independent core laboratory (Japan Cardiocore, Tokyo, Japan) and assessed by experts blinded to patient data. The MDCT images of the aortic root were determined with dedicated software for aortic valve assessment (the automated 3mensio™ Valves 5.1, sp1, 3mensio; Pie Medical Imaging BV, Maastricht, The Netherlands). All MDCT measurements have been performed at 30% of the RR interval. The annulus surface area was then manually traced and the orthogonal long annulus diameter, short annulus diameter, and the

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height of the coronary ostia were measured. The valve eccentricity index was calculated as: (1 – short annulus diameter/long annulus diameter)×100, according to the method previously described by Blanke et al[6]. Aortic root calcification volume was measured using the algorithm of 3mensio software, which has been described previously[7]. The Hounsfield unit threshold is defined by individually adjusting the calcification area measurements obtained by 3mensio imaging. Contrast agent was used in this procedure. The term aortic root refers to the aortic valve from its insertion at the left ventricular outlet to the sinotubular junction. The CT annulus assessments were performed by three experienced cardiac CT observers (Y. Watanabe, T. Tsunaki, and F. Yashima). All observers were highly experienced in MDCT valvular assessments (level of proficiency 3) according to the American College of Cardiology/American Heart Association statement on competency in cardiac CT imaging[8].

INTEROBSERVER AND INTRAOBSERVER AGREEMENT

Retrieved from 14 randomly selected data files, aortic annulus diameters were re-measured by another observer to determine interobserver agreement and by the same observer subsequently to determine intraobserver agreement. All observers were blinded to previous measurements.

STATISTICAL ANALYSIS

Quantitative variables were assessed for normal distribution with the Shapiro-Wilk test and are expressed as mean±standard deviation or as median and interquartile range (IQR: 25-75%), as appropriate. Qualitative variables are expressed as numeric values and percentages. Comparison of quantitative variables was performed using the unpaired Student's t-test or the Wilcoxon rank-sum test, depending on the variable distribution. The chi-square test or Fisher's exact test was used to compare qualitative variables. Pearson correlations were used to compare between the aortic annulus area, or perimeter and body surface area (BSA) in both the Japanese and European cohorts. In addition, intraobserver and interobserver agreement was evaluated for the aortic annulus measurement by calculating the intraclass correlation coefficients (ICCs), with excellent agreement defined as an ICC >0.8. The data were analysed with PASW statistics, Version 19.0 (IBM Corp., Armonk, NY, USA).

Results

PATIENT CHARACTERISTICS

The baseline characteristics of the two study groups are presented in **Table 1**. Female sex was more frequently observed in the Japanese cohort (74.4% vs. 44.2%, p<0.01). Body size area (BSA) and body mass index (BMI) were significantly smaller among Japanese patients than those in the European cohort (1.40±0.15 vs. 1.76±0.19 m², p<0.01; 22.5±3.1 vs. 25.8±4.0 kg/m², p<0.01, respectively). The rate of NYHA Class III or IV and previous pacemaker placement were significantly lower among the Japanese patients (47.8% vs. 88.4%, p<0.01; 5.6% vs. 15.2%, p<0.02, respectively). Higher rates of previous percutaneous coronary intervention and cerebrovascular disease were observed in the Japanese patients (38.9% vs. 23.8%, p<0.01; 15.7% vs. 7.8%, p=0.02, respectively). The value of the estimated glomerular filtration rate, STS score, and left ventricular ejection fraction were higher among the Japanese patients (46.5 [IQR 35.8-57.3] vs. 56.2 [IQR 41.7-70.8], p<0.01; 6.9 [IQR 4.6-9.2] vs. 5.6 [IQR 3.1-8.2], p<0.01; 65.0% [IQR 59.9-70.1%] vs. 56.0% [IQR 43.5-8.5%], p<0.01, respectively).

Table 1. Baseline characteristics of the study population, Japanese registry vs. European study group.

	Japanese	European	*p*-value
No. of patients	90	181	
Age, years	85 (82.5-87.5)	84 (80.5-87.5)	0.83
Male sex	23 (25.6%)	101 (55.8%)	<0.01
Height, cm	147.6±9.5	164.2±8.4	<0.01
Weight, kg	49.0±8.1	69.8±13.2	<0.01
BSA, m²	1.40±0.15	1.76±0.19	<0.01
BMI, kg/m²	22.5±3.1	25.8±4.0	<0.01
Diabetes	28 (31.1%)	40 (22.1%)	0.11
Hyperlipidaemia	49 (54.4%)	87 (48.1%)	0.32
Hypertension	65 (72.2%)	124 (68.5%)	0.53
NYHA Class III/IV	43 (47.8%)	160 (88.4%)	<0.01
Previous pacemaker	5 (5.6%)	15 (15.2%)	0.02
Coronary artery disease	42 (46.7%)	98 (54.1%)	0.25
Previous MI	10 (11.1%)	12 (6.7%)	0.21
Previous PCI	35 (38.9%)	43 (23.8%)	0.01
Previous CABG	7 (7.8%)	17 (9.4%)	0.65
Peripheral artery disease	23 (25.6%)	60 (33.5%)	0.18
Cerebrovascular disease	14 (15.7%)	14 (7.8%)	0.05
COPD	19 (21.1%)	37 (20.7%)	0.93
eGFR	46.5 (35.8-57.3)	56.2 (41.7-70.8)	<0.01
Logistic EuroSCORE, %	16.4 (9.5-23.3)	15.5 (7.7-23.3)	0.53
STS score, %	6.9 (4.6-9.2)	5.6 (3.1-8.2)	<0.01
Aortic valve area, cm²	0.60 (0.47-0.73)	0.63 (0.52-0.74)	0.62
Mean pressure gradient, mmHg	42.0 (29.9-54.2)	45.0 (36.5-53.5)	0.11
LVEF, %	65.0 (59.9-70.1)	56 (43.5-68.5)	<0.01

Values are expressed as n (%) or mean±SD or median and interquartile range. BMI: body mass index; CABG: coronary artery bypass graft; COPD: chronic obstructive pulmonary disease; eGFR: estimated glomerular filtration rate; LVEF: left ventricular ejection fraction; MI: myocardial infarction; NYHA: New York Heart Association; PCI: percutaneous coronary intervention; PVL: paravalvular leak

MDCT characteristics

The pre-TAVI cardiac MDCT characteristics are presented in **Table 2**. Short- and long-axis annulus diameters were significantly smaller among Japanese patients (19.4±2.0 mm vs. 22.6±2.3 mm, p<0.01; 24.7±1.9 mm vs. 27.6±2.5 mm, p<0.01, respectively). A more eccentric annulus presented as the eccentricity index was observed more frequently in Japanese patients (21.5±6.2 vs. 18.9±5.3, p<0.01). A shorter annulus perimeter and smaller annulus area were observed among Japanese patients (70.3±5.0 mm vs. 80.4±7.0 mm, p<0.01; 375.9 mm² [IQR 333.8-410.7] vs. 472.5 mm² [IQR 415.3-536.6], p<0.01, respectively). **Figure 1** shows the

Table 2. Patient and cardiac CT characteristics, Japanese registry vs. European study group.

	Japanese	European	*p*-value
No. of patients	90	181	
Short-axis annulus diameter, mm	19.4±2.0	22.6±2.3	<0.01
Long-axis annulus diameter, mm	24.7±1.9	27.6±2.5	<0.01
Eccentricity index	21.5±6.2	18.9±5.3	<0.01
Perimeter, mm	70.3±5.0	80.4±7.0	<0.01
Area, mm^2	375.9 (333.8-410.7)	472.5 (415.3-536.6)	<0.01
Area/BSA, mm^2	268.8±36.9	271.8±44.8	0.59
Left coronary height, mm	13.6 (12.0-15.0)	15.1 (13.5-17.2)	<0.01
Right coronary height, mm	15.9 (14.5-17.5)	17.7 (16.0-19.7)	<0.01
Sinus of Valsalva, mm	27.2 (25.6-29.5)	32.0 (29.7-34.0)	<0.01
Sinus of Valsalva height, mm	8.9 (8.0-9.9)	11.5 (10.3-12.6)	<0.01
Shortest diameter of STJ, mm	24.3±2.6	28.2±3.1	<0.01
STJ height, mm	19.3±2.3	22.9±2.9	<0.01
Total aortic valve calcification volume, mm^3	606.4 (378.0-923.3)	740.0 (448.0-1,064.0)	0.07
Ratio calcification/BSA	438.1 (272.4-641.6)	409.7 (262.0-618.5)	0.36

Values are expressed as n (%) or mean±SD or median (interquartile range). BSA: body surface area; STJ: sinotubular junction

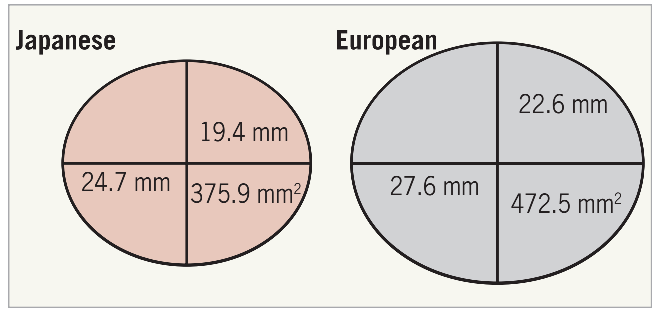

Figure 1. *Comparison of aortic annulus mean diameters between the Japanese and European cohorts. The annulus diameters of Japanese patients were smaller and more eccentric than those of the European patients.*

comparison of aortic annulus mean diameters between patients in the Japanese and the European cohorts. **Figure 2** and **Figure 3** show the comparison of aortic annulus area and perimeter between patients in the Japanese and the European cohorts.

The left coronary height and right coronary height were significantly shorter among Japanese patients (13.6 mm [IQR 12.0-15.0] vs. 15.1 mm [IQR 13.5-17.2], p<0.01; 15.9 mm [IQR 14.5-17.5] vs. 17.7 mm [IQR 16.0-19.7), p<0.01]. **Figure 4** shows the distribution of left coronary heights.

The sinus of Valsalva (SOV), SOV height, sinotubular junction (STJ), and STJ height were smaller in the Japanese patients, suggesting that these patients had a shallow shape of the SOV (27.2 mm [IQR 25.6-29.5] vs. 32.0 mm [IQR 29.7-34.0], p<0.01; 8.9 mm [IQR 8.0-9.9] vs. 11.5 mm [IQR 10.3-12.6], p<0.01; 24.3±2.6 mm vs. 28.2±3.1 mm, p<0.01; 19.3±2.3 mm vs. 22.9±2.9 mm, p<0.01, respectively). **Table 3** shows the risk of coronary occlusion after TAVI, using the threshold data described by Ribeiro et al[9]. According to these threshold data, Japanese patients had a higher risk of coronary occlusion.

No significant differences were observed in total aortic valve calcification volume (606.4 mm^3 [IQR 378.0-923.3] vs. 740.0 mm^3 [IQR 448.0-1,064.0], p=0.07), even when adjusted for BSA (438.1 [IQR 272.4-641.6] vs. 409.7 [IQR 262.0-618.5], p=0.36).

Table 4 shows the gender difference of cardiac CT characteristics, Japanese registry vs. European study group. The short- and long-axis annulus diameter, SOV, and STJ were smaller among Japanese patients compared with European patients, both female and male. Japanese female patients had smaller left coronary height

Table 3. Risk of coronary occlusion after TAVI, using the threshold data from Ribeiro et al.

	Japanese	European	*p*- value
No. of patients	90	181	
Aortic SOV diameter <28.3 mm	60 (66.7%)	17 (13.9%)	<0.01
Ratio SOV/CAAD <1.26	43 (47.8%)	41 (33.6%)	0.04
Left coronary height <10.7 mm	12 (13.3%)	7 (3.9%)	<0.01
Right coronary height <12.7 mm	7 (7.8%)	4 (2.2%)	0.03

Values are expressed as n (%) or mean±SD. CAAD: calculated average annulus diameter; SOV: sinus of Valsalva

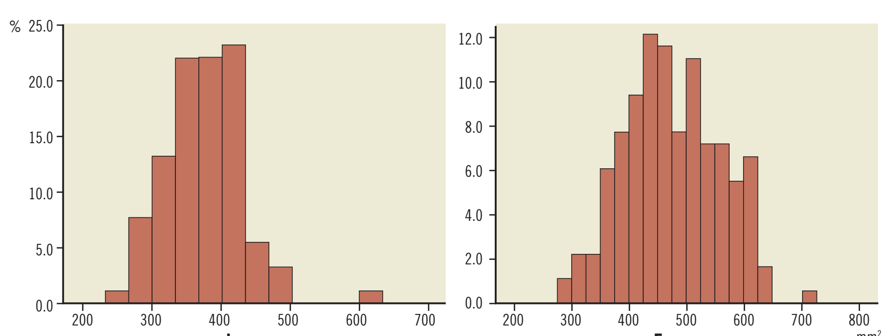

Figure 2. *The distribution of CT measurements of aortic annulus area, Japanese and European cohorts.*

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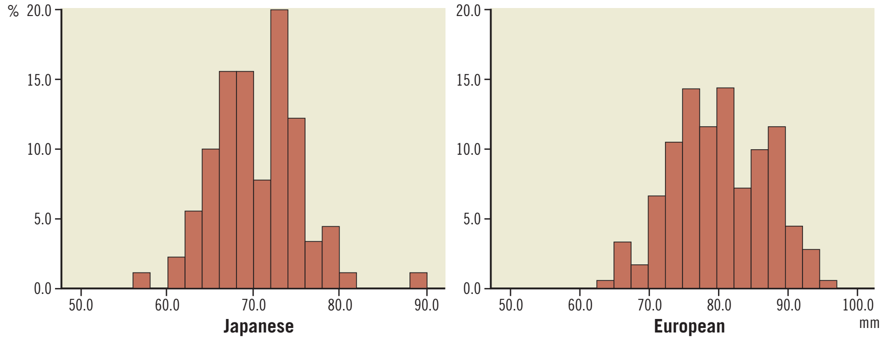

Figure 3. *The distribution of CT measurements of aortic annulus perimeter, Japanese and European cohorts.*

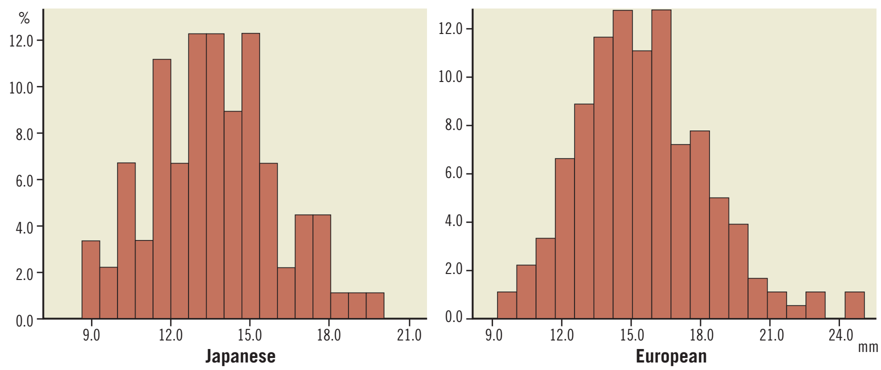

Figure 4. *The distribution of CT measurements of left coronary height, Japanese and European cohorts.*

(13.1±2.1 mm vs. 14.5±2.3 mm, p<0.01) and a more elliptical annulus (eccentricity index 22.3±6.3 vs. 19.1±5.8, p<0.01) compared with European female patients.

CORRELATION BETWEEN THE AORTIC ANNULUS AREA OR THE PERIMETER AND BSA IN BOTH THE JAPANESE AND EUROPEAN COHORTS

Correlations between the aortic annulus area or the perimeter and BSA in the Japanese cohort were moderate (r=0.41, p<0.01, and r=0.45, p<0.01, respectively) **(Figure 5)**. Correlations between the aortic annulus area or the perimeter and BSA in the European cohort were also moderate (r=0.42, p<0.01, and r=0.45, p<0.01, respectively) **(Figure 6)**.

INTEROBSERVER AND INTRAOBSERVER REPRODUCIBILITY

The ICC for the interobserver and intraobserver reproducibility was satisfactory for the measurement of the aortic annulus area (intraobserver ICC 0.98, interobserver ICC 0.95, respectively) and the perimeter (intraobserver ICC 0.96, interobserver ICC 0.94, respectively).

Table 4. Gender difference of cardiac CT characteristics, Japanese registry vs. European study group.

	Female n=147			Male n=124		
	Japanese n=67	European n=80	*p*-value	Japanese n=23	European n=101	*p*-value
BSA, m²	1.35±0.12	1.65±0.15	<0.01	1.54±0.10	1.85±0.17	<0.01
Short-axis annulus diameter, mm	18.7±1.7	21.0±2.0	<0.01	21.2±1.9	23.3±1.6	<0.01
Long-axis annulus diameter, mm	24.2±1.7	25.9±2.2	<0.01	26.1±1.8	28.9±2.0	<0.01
Eccentricity index	22.3±6.3	19.1±5.8	<0.01	18.9±5.3	19.4±5.2	0.66
Left coronary height, mm	13.1±2.1	14.5±2.3	<0.01	15.1±2.6	16.2±3.0	0.13
Right coronary height, mm	15.7±2.6	16.4±2.2	0.06	18.2±2.8	18.9±2.3	0.18
SOV, mm	26.5±1.8	29.4±2.3	<0.01	30.7±2.1	33.8±2.9	<0.01
STJ, mm	23.7±2.2	26.3±2.1	<0.01	26.2±2.6	29.4±3.0	<0.01
Total aortic valve calcification volume, mm³	534.0 (268.3-799.7)	545.3 (315.1-775.5)	0.95	780.0 (472.4-1,087.6)	820.4 (495.2-1,145.6)	0.59

Values are expressed as n (%) or mean±SD or median (interquartile range). BSA: body surface area; SOV: sinus of Valsalva; STJ: sinotubular junction

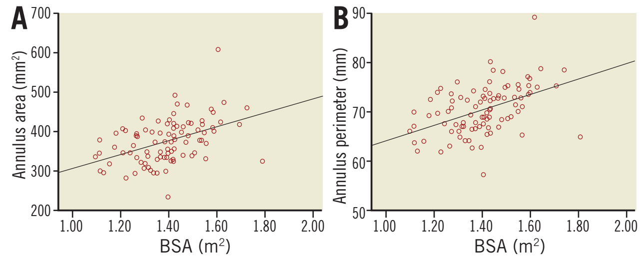

Figure 5. *Correlation between the aortic annulus area or perimeter and BSA in the Japanese cohort. A) Correlation between the annulus area and the BSA was moderate (r=0.41, p<0.01). B) Correlation between the annulus perimeter and the BSA was moderate (r=0.45, p<0.01).*

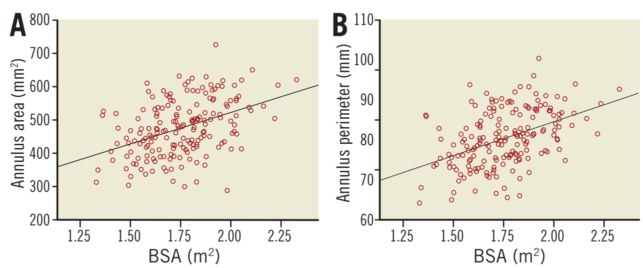

Figure 6. *Correlation between the aortic annulus area or perimeter and BSA in the European cohort. A) Correlation between the annulus area and the BSA was moderate (r=0.42, p<0.01). B) Correlation between the annulus perimeter and the BSA was moderate (r=0.45, p<0.01).*

Discussion

This study is the first direct comparison of aortic annulus dimensions measured by MDCT between Japanese and European patients undergoing TAVI. Nearly all of the measured annulus dimensions were smaller in the Japanese patients than in the European patients. The majority of patients were of female gender in the Japanese cohort, and Japanese female patients had smaller aortic annulus dimensions compared to European female patients. A smaller size of transcatheter valve would be required for Japanese patients.

Difference in physique and race may cause the differences in the diameter of the aortic annulus and in valve sizing. A previous report showed that patients with small body size had smaller annulus and valve size[10]. A comparison of clinical outcomes between European and Japanese cohorts undergoing TAVI demonstrated that Japanese patients had a smaller aortic annulus as shown on echocardiography, and that the most commonly used implant was the Edwards 23 mm valve in the Japanese group and the Edwards 26 mm valve in the European group, suggesting that smaller valves are needed for Asian patients[11].

In the current study, all the annulus dimensions determined using MDCT were smaller among Japanese patients. Patients with a small aortic annulus have a potential risk of prosthesis oversizing and annulus rupture. The introduction of smaller valves such as a 20 mm balloon-expandable transcatheter heart valve may contribute to reducing the risk of annulus rupture in Asian patients with a smaller annulus[12]. Another risk factor for annulus rupture is the amount and distribution of calcification in the aortic annular complex[13,14]. In the current study, no significant differences were observed in terms of aortic valve calcification volume between the European and Japanese cohorts. Although the amount of calcification volume was the same between the two cohorts, patients with a smaller annulus still have a higher risk of annulus rupture.

An elliptical aortic annulus was more frequently seen among Japanese patients. A previous study reported that implantation of the Edwards SAPIEN XT transcatheter valve into elliptical aortic annuli leads to increased paravalvular leakage *in vitro*[15]. Non-circular aortic annuli may cause valve undersizing and pose a risk of annulus rupture unless MDCT is used for measurement[16,17]. Thus, MDCT imaging techniques are more crucial to the evaluation of aortic annulus diameters, especially in patients with an elliptical aortic annulus.

Shorter coronary height from the annulus plane was observed among Japanese patients. Ribeiro et al reported on data from a multicentre registry, which showed that a lower-lying coronary ostium and a shallow SOV were associated with coronary obstruction after TAVI[9]. In the current study, the diameter and height of SOV were shorter in the Japanese group and had a shallow shape, suggesting the existence of racial differences between Japanese and European patients and the potential risk of coronary obstruction after TAVI. In addition, Japanese female patients had smaller left coronary height compared with European female patients. Considering female sex was more frequently observed in the Japanese cohort, special attention to coronary obstruction is needed for Japanese patients during TAVI. Prevention of coronary occlusion using, for example, coronary protection with prior wire placement into the coronary before valve implantation may be a valuable solution[18]. In the registry data, the coronary obstruction rate was more than twice as high among patients who received a balloon-expandable valve than among those who received a self-expanding valve (0.81% vs. 0.34%)[9]. The CoreValve (Medtronic, Minneapolis, MN, USA) system will be suitable for the Japanese patients with a risk of coronary obstruction; however, attention will be needed for the small SOV with a potential risk of coronary obstruction. Anatomical risks of TAVI in Japanese patients are shown in **Figure 7**.

The TAVI procedure has reached relative maturity in European countries, whereas in some Asian countries clinical trials have just concluded and TAVI has started to be used commercially. We believe that our study provides important data in terms of measuring the dimension of the aortic annulus and valve sizing, leading to improved safety and outcomes for Asian patients undergoing TAVI.

Limitations

This non-randomised observational study compared the results between a clinical registry in Japan and a single-centre experience in Europe. Furthermore, because it was a single-centre experience, results from the European cohort do not represent results from all of Europe. The ethnicity of the French cohort was not all Caucasian.

Patient selection bias exists because CT data of only 33% of patients were available in the European cohort. Patient treatment

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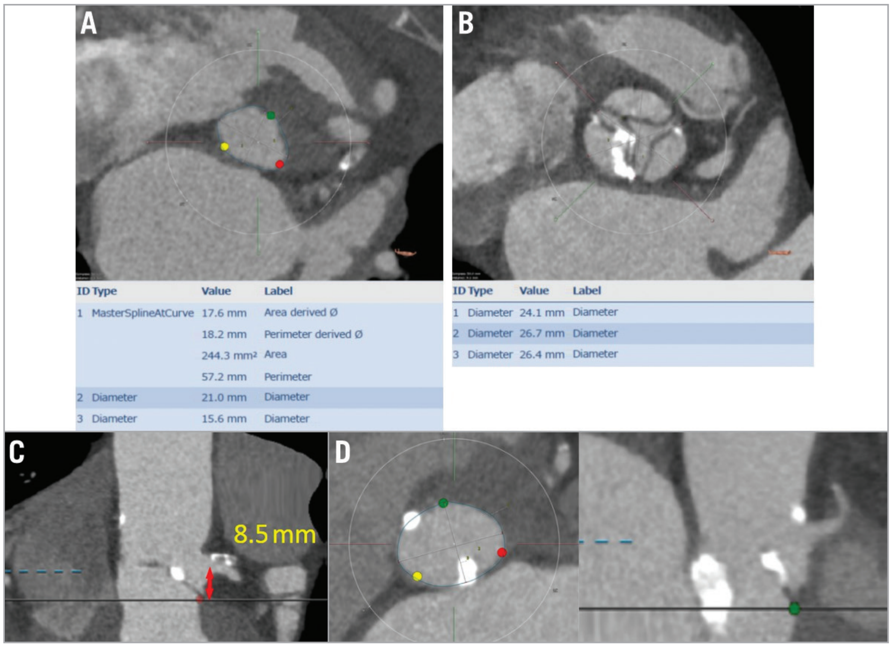

Figure 7. *Anatomical risks of TAVI in Japanese patients. A) Smaller aortic annulus area. B) Smaller diameter of sinus of Valsalva. C) Shorter height of coronary artery. D) Calcified aortic valve.*

bias is inherent in non-randomised observational studies and may have affected the comparison of clinical outcomes between the OCEAN-TAVI cohort and the European single-centre cohort. Procedures on patients in the OCEAN-TAVI cohort are proctored by representatives of the Edwards Company. Thus, patient selection is probably different from that of the selection process for patients in the European cohort. Furthermore, only 23 mm and 26 mm Edwards SAPIEN XT prostheses were available in Japan at the time of this study. Patients with an aortic annulus not suitable for these two available valves were not considered TAVI candidates and were excluded from this study.

Female sex was more frequently observed in the Japanese cohort. In general, Japanese women have a long life expectancy, and therefore female sex was more frequently observed in the Japanese cohort. Japanese male AS patients were likely to have been operated on before consideration for TAVI.

Further studies of a larger group of patients will be required to confirm our results.

Conclusion

Japanese patients had smaller annulus dimensions by MDCT compared with European patients. The risks related to these anatomical characteristics should be taken into consideration for Japanese patients undergoing TAVI.

Impact on daily practice

This study will provide important data for valve selection and sizing for the smaller aortic anatomy of Asian patients undergoing TAVI.

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Conflict of interest statement

Y. Watanabe is a proctor for transfemoral TAVI for the Edwards Company. M. Yamamoto is a proctor for transfemoral TAVI for the Edwards Company. T. Lefèvre is a proctor for transfemoral TAVI for the Edwards Company and is a consultant for Symetis and Direct Flow Medical. K. Hayashida is a proctor for transfemoral TAVI for the Edwards Company. The other authors have no conflicts of interest to declare.

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